

Atty. Docket No.:

4231/2032

**PATENT** 

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Liew, et al.

Serial No.:

10/649,959

Filed:

August 26, 2003

Entitled:

"Beta-2 Microglobulin (B2M) and

B2M Related Gene Products for the

Regulation of Osteoarthritis Pathogenesis and Chondrocyte

Proliferation"

Examiner:

Not Yet Assigned

Group Art Unit:

Not Yet Assigned

Conf. No.:

Not Yet Assigned

### **CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8a**

I hereby certify that this correspondence (and any paper or fee referred to as being enclosed) is being deposited with the United States Post Office as First Class Mail on the date indicated below in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Brenda M. Woods

Name of Person Mailing Paper

Signature of Person Mailing Paper

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

## TRANSMITTAL LETTER

Enclosed for filing in the above-identified patent application, please find the following documents:

- 1. Information Disclosure Statement;
- 2. Form PTO-1449;
- 3. Copies of Cited References; and
- 4. Return Post Card.

The Commissioner for Patents is hereby authorized to charge any additional fees or credit any overpayment in the total fees to Deposit Account No. 16-0085, Reference No. 4231/2032. <u>A duplicate of this transmittal letter is enclosed for this purpose.</u>

Respectfully submitted,

Date: October 30, 2003

Name: Mark J. FitzGerald Registration No.: 45,928 Palmer & Dodge LLP 111 Huntington Avenue Boston, MA 02199-7613

Tel: 617-239-0100

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# INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§§ 1.56, 1.97 AND 1.98

Dear Sir:

In accordance with the duty of disclosure under 37 CFR § 1.56, Applicant submits this Information Disclosure Statement pursuant to 37 CFR §§ 1.97 and 1.98 in the above-identified application for consideration by the Patent Office.

A listing of the cited documents is also enclosed, as well as, for the Examiner's convenience, copies of the documents in the list.

Pursuant to CFR § 1.97(b)(3), because this Statement is being submitted before the first Office Action on the merits, no fee is required.

Applicant does not intend to represent that any of the documents submitted herein are material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicant respectfully requests that the documents submitted herein be considered and made of record in this application.

Respectfully submitted,

Date: October 30, 2003 Name: Mark J. FitzGerald Registration No.: 45,928 Palmer & Dodge LLP 111 Huntington Avenue Boston, MA 02199-7613

Tel: 617-239-0100

USPTO Form 1449 Patent and Trademark Office  INFORMATION DISCLOSURE STATEMENT				Attorney Docket No.		Serial No.		
				4231/2032 10/649,959				
				Applicant(s):. Liew, et al.  Filing Date: August 26, 2003			Group: Not Yet Assigned	
U.S. PAT	ENT DO	DCUMENTS						
Examiner Initial		Patent No.	Date	Name	Class	Subclass	Filing I (if approp	
FOREIGN	N PATE	NT DOCUMENTS						<del></del>
Examiner Initial		Document No.	Publication Date	Country	Class	Subclass	Translation	
							YES	NO
OTHER I	OOCUM	IENTS (including Auth	or, Title, Date, Pert	inent Pages, etc.)				
	1.				sis", Patho	ol Int, (200	01); 51:1-1	0.
	2.	Ohashi, K., "Pathogenesis of β <sub>2</sub> -microglobulin amyloidosis", <i>Pathol Int</i> , (2001); 51:1-10.  Moe, S.M. et al., "β <sub>2</sub> -Microglobulin induces MMP-1 but not TIMP-1 expression in human synovial fibroblasts", <i>Kidney International</i> , (2000), 57:2023-2034.						
	3.	Rodriguez, J. et al., "Serum β <sub>2</sub> -Microglobulin Levels Are a Significant Prognostic Factor in Philadelphia Chromosome-positive Chronic Myelogenous Leukemia", <i>Clin Cancer Res</i> , (2000), 6:147-152.						
	4.	Cantatore, F.P. et al., "Evaluation of Bone Turnover and Osteoclastic Cytokines in Early Rheumatoid Arthritis Treated with Alendronate", <i>J Rheumatol.</i> , (1999), 26:2318-2323.						
	5.	Migita, K. et al., "Induction of cyclooxygenase-2 in human synovial cells by β <sub>2</sub> -microglubulin", <i>Kidney International</i> , (1999), 55:572-578.						
	6.	Migita, K. et al., "β <sub>2</sub> -Microglobulin Induces Stromelysin Production by Human Synovial Fibroblasts", <i>Bioch. and Biophy. Res. Commu.</i> , (1997), 239:621-625.						
	7.	Söderblom, T. et al., "Pleural Fluid Beta-2-Microglobulin and Angiotensin-Converting Enzyme Concentrations in Rheumatoid Arthritis and Tuberculosis", <i>Respiration</i> , (1996), 63:272-276.						
	8.	Bindi, P., et al., "Destructive Spondyloarthropathy in Dialysis Patients: An Overview", <i>Nephron</i> , (1990), 55:104-109.						
	9.	Brinckerhoff, C.E. et al., "Autocrine Induction of Collagenase by Serum Amyloid A-Like and β <sub>2</sub> -Microglubulin-Like Proteins", <i>Science</i> , (1989), 243:655-657.						
	10.	Homma, N. et al., "Collagen-Binding Affinity of Beta-2-Microglobulin, a Preprotein of Hemodialysis-Associated Amyloidosis", <i>Nephron</i> , (1989), 53:37-40.						
	11.	microglobulin and	C reactive protein	Serum and synovial in relation to clinic ", Ann Rheum Dis, (	al disease	activity ar	• -	

12.	Hoelsman, J.H., et al., "Specific Associations of Fluorescent β-2-Microglobulin with Cell Surfaces", <i>J Immunol</i> , (1988), 140:2322-2329.				
13.	Revillard, J.P. et al., "Structure and Metabolism of Beta-2-Microglobulin", <i>Contrib Nephrol</i> , (1988), 62:44-53.				
14.	Schardijn, G.H. et al., "β <sub>2</sub> -microglobulin: Its significance in the evaluation of renal function", <i>Kidney Int</i> , (1987), 32:635-641.				
15.	Bardin, T. et al., "Synovial Amyloidosis in Patients Undergoing Long-Term Hemodialysis", <i>Arthritis Rheum</i> , (1985), 28(9):1052-1058.				
16.	Gejyo, F. et al., "A New Form of Amyloid Protein Associated with Chronic Hemodialysis was Identified as β <sub>2</sub> -Microglobulin", <i>Biochem Biophys Res Commun</i> , (1985), 129(3):701-706.				
17.	Bernabeu, C. et al., "β <sub>2</sub> -Microglobulin from serum associates with MHC class I antigens on the surface of cultured cells", <i>Nature</i> , (1984), 308:642-645.				
18.	Bataille, R. et al., "Serum beta <sub>2</sub> microglobulin and survival duration in multiple myeloma: a simple reliable marker for staging", <i>Br J Haematol</i> , (1983), 55:439-447.				
ER		DATE CONSIDERED			
	13. 14. 15. 16. 17.	<ol> <li>Revillard, J.P. et al., "Structure and Metabolism of Beta-2-(1988), 62:44-53.</li> <li>Schardijn, G.H. et al., "β<sub>2</sub>-microglobulin: Its significance in Kidney Int, (1987), 32:635-641.</li> <li>Bardin, T. et al., "Synovial Amyloidosis in Patients Undergatheritis Rheum, (1985), 28(9):1052-1058.</li> <li>Gejyo, F. et al., "A New Form of Amyloid Protein Associal Identified as β<sub>2</sub>-Microglobulin", Biochem Biophys Res Com Bernabeu, C. et al., "β<sub>2</sub>-Microglobulin from serum associate the surface of cultured cells", Nature, (1984), 308:642-645.</li> <li>Bataille, R. et al., "Serum beta<sub>2</sub> microglobulin and survival simple reliable marker for staging", Br J Haematol, (1983)</li> </ol>			

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

<sup>\*\*</sup>Copies of references not provided at the time of this submission.